DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 29, 2015

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Ms. Phuong Chau
Senior Regulatory Affairs Product Specialist
9775 Toledo Way
Irvine, California 92618

Re: K150107
Trade/Device Name: Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 26, 2015
Received: June 29, 2015

Dear Ms. Phuong Chau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150107

Device Name
Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter

Indications for Use *(Describe)*
The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K150107

510(k) Owner: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Contact Person: Phuong Chau
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Date Summary Prepared: June 25, 2015

Trade Name of Device: Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter

Common Name of Device: Catheter, Percutaneous

Classification of Device: 21 CFR 870.1250 – Class II

Product Code: DQY

Predicate Device: ReFlex™ Guide Catheter, 510(k)#: K110055

Performance Data: The following bench testing was performed in support of the Arc™ and Arc™ Mini Intracranial Support Catheter and to establish substantial equivalence to the ReFlex™ Guide Catheter:

- Lumen Patency
- Dimensional Inspection
- Distal Tip Buckling
- Catheter Injection Flow Rate
- Catheter Suction Flow Rate
- Vacuum Resistance
- Hub Air Aspiration Leak
- Shaft Peak Tensile Force
- Hub Peak Tensile Force
- Coating Integrity – Baseline
- Coating Lubricity/Durability

- Particulate Testing
- Coating Integrity – Simulated Use
- Kink Resistance
- Liquid Leakage
- Static/Dynamic Burst
- Torque to Failure

A Design Validation study was performed on a bench model to assess the usability of the Arc™ and Arc™ Mini Intracranial Support Catheter compared to the previously cleared ReFlex™ Guide Catheter. Biocompatibility testing, sterilization, and a 6-month accelerated aging study were also performed. No clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology of the device.

Conclusion: The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are substantially equivalent to the currently cleared ReFlex™ Guide Catheter based on the successful completion of non-clinical bench and design validation testing as well as similar principles of design, operation and indications for use.

Device Description:

The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are designed for the introduction of interventional devices into the peripheral and neurovasculature. The Arc™ and Arc™ Mini are a single lumen, flexible, variable stiffness composite catheters with a Nitinol structure. A radiopaque marker band on the distal tip of the devices is used for visualization under fluoroscopy. The distal sections of both catheters are coated with a hydrophilic coating, which is used to reduce the overall frictional force during intravascular use. The Arc™ and Arc™ Mini dimensions are included in the individual device label. The devices are supplied sterile and are intended for single-use only.

Indications for Use:

The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Device Comparison

The table below provides a comparison of the technological characteristics of the Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter and the currently cleared ReFlex™ Guide Catheter.

	ReFlex™ Guide Catheter (K110055)	**Arc™ Intracranial Support Catheter**	**Arc™ Mini Intracranial Support Catheter**	**Rationale for Difference (If Present)**
Indication for Use	The ReFlex™ Guide Catheter is indicated for the introduction of	The Arc Intracranial Support Catheter is indicated for the introduction of	The Arc Mini Intracranial Support Catheter is indicated for the introduction	N/A

	ReFlex™ Guide Catheter (K110055)	Arc™ Intracranial Support Catheter	Arc™ Mini Intracranial Support Catheter	Rationale for Difference (If Present)
	interventional devices into the peripheral and neurovasculature.	interventional devices into the peripheral and neurovasculature.	of interventional devices into the peripheral and neurovasculature.	
Materials				
Catheter Shaft Materials	PTFE lined polymeric catheter, with hydrophilic coating	PTFE lined polymeric catheter, with hydrophilic coating	PTFE lined polymeric catheter, with hydrophilic coating	The material used for the Arc and Arc Mini catheters were shown to be biocompatible per ISO 10993 testing. Materials of this type are widely used in similar medical devices.
Catheter Shaft Support	Nitinol	Same	Same	N/A
Marker band	Platinum	Same	Same	N/A
Dimensions				
Usable Length	90 – 130 cm	132 – 135 cm	160 – 163 cm	Longer lengths provided for additional navigability options to user.
Distal ID	0.046” – 0.072”	0.061”	0.035”	Smaller distal ID provided for improved trackability over guide wire to smaller vessels.
Distal OD (Max)	0.058”– 0.084” max	0.071” max	0.049”	Smaller distal ID/OD provided for improved distal flexibility.
Proximal ID	0.046” – 0.072”	0.069”	0.044”	Smaller proximal ID provided for improved trackability over guide wire to

	ReFlex™ Guide Catheter (K110055)	Arc™ Intracranial Support Catheter	Arc™ Mini Intracranial Support Catheter	Rationale for Difference (If Present)
				smaller vessels.
Proximal OD (Max)	0.058"– 0.084" max	0.0825" max	0.0620"	N/A
Tip Configuration	Single, straight flexible tip	Same	Same	N/A
Guidewire Compatibility	Can be navigated over a guidewire with a maximum OD of 0.038 in.	Same	Can be navigated over a guidewire with a maximum OD of 0.032 in.	Largest compatible guidewire size dependent on smallest ID.
Sterilization Method	Ethylene Oxide	Same	Same	N/A
Packaging	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton	Same	Same	N/A

Sterilization and Shelf Life

The packaged Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are sterilized using a validated ethylene oxide (EO) sterilization cycle at the Sterigenics US; LLC facility located at 4900 Gifford Avenue, Los Angeles, CA. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1:2007, *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.*

Aging studies for the Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter devices have established the product and packaging remain functional and maintain sterility for up to 6 months. Aging studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility testing was performed in compliance with the FDA consensus standard, recognition number 2-156, AAMI/ANSI/ISO 10993-1: 2009, Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process and U.S. Food and Drug Administration (FDA) Blue Book Memorandum G95-1 (1995) guidelines. All studies were conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58.

Test	Result	Conclusion
Plastics (USP)	Meets USP Physicochemical extraction parameters.	Passes physical chemical characteristics.
L929 MEM Elution Test – ISO	The test article scored "0" at 24, 48 and 72 ± 4 hours and is considered non-cytotoxic under the conditions of this test.	Non-cytotoxic
Klingman Maximization Test – ISO (Guinea Pig Sensitization)	Under the conditions of this protocol, the test article did not elicit a sensitization response.	Non-sensitizer
Intracutaneous Injection Test - ISO	The differences in the mean test and control scores of the extract dermal observations were less than 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.	Non-irritant
Acute Systemic Injection Test – ISO	None of the test article extract treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	Non-cytotoxic
Materials Mediated Rabbit Pyrogen – ISO	This response did not exceed the USP limit and meets the requirements for this test. Therefore these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic
Hemolysis: Direct Contact / Indirect Extract	There were no significant differences between the test article extract and negative control article results. The test article is considered non-hemolytic	Non-hemolytic
Complement activation C3a and SC5b-9	The levels of C3a and SC5b-9 of the Dyson catheter are comparable to the ReFlex and less than that of the positive control.	Levels of the compliments C3a and SC5b complements were similar for Arc and control device
Thrombosis (*in vivo*) – Canine (Arc / ReFlex)	The thromboresistance properties of the Arc and Arc Mini Intracranial Support Catheters are acceptable in clinical use.	Acceptable, expected to be equivalent to ReFlex in clinical use
in vitro Hemocompatibility Assay	Neither the Arc nor the ReFlex Guide Catheter resulted in a decrease in any blood component	No adverse effect on platelet and leukocyte counts

Test	Result	Conclusion
	as compared to the reference material. These results indicate that the cause of thrombi is not related to the materials exposed to human blood during use.	
Partial Thromboplastin Time	Clotting times for Arc and the ReFlex (predicate device) test arms were similar to the negative control and the reference material (HDPE), indicating that the device materials are not an activator of the intrinsic coagulation pathway.	No adverse effect on prothrombin coagulation time of human plasma.
Ames bacterial Mutagenicity 4 salmonella+1e.coli	Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic.	Non-mutagenic
in vitro Mouse Lymphoma Assay with Extended Treatment	The test article is considered to be non-mutagenic (non-genotoxic and non-clastogenic) in this test system.	Non-mutagenic
in vivo Mouse Micronucleus Assay	Based on the criteria of the assay, the test article is considered non-mutagenic in this test system.	Non-mutagenic

Performance Testing – Bench

A summary of the pre-clinical bench testing performed for the Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter is presented in the table below.

Test	Method	Conclusions
Lumen Patency	The total length of the device must pass a mandrel of the required size from the proximal hub to distal tip.	All devices met acceptance criteria.
Dimensional Inspection	The usable length, proximal and distal inner and outer diameters were measured and recorded.	All device met acceptance criteria.
Distal Tip Buckling	Repeated distal tip buckling force under compressive load was evaluated for stiffness.	Distal tip buckling force met acceptance criteria.
Catheter Injection Flow Rate	Device flow rate was measured using ISO 10555-1, Annex E test methods with injection through proximal hub.	Injection flow rate met acceptance criteria.

Test	Method	Conclusions
Catheter Suction Flow Rate	Device flow rate was measured using ISO 10555-1, Annex E test methods with injection through distal tip.	Suction flow rate met acceptance criteria.
Vacuum Resistance	Device was evaluated for resistance to vacuum collapse under static conditions with a 60cc syringe.	Device was resistant to vacuum collapse under static conditions.
Hub Air Aspiration Leak	Device was tested for ISO 10555-1, Annex D hub air aspiration leak.	Hub air aspiration test met acceptance criteria.
Shaft Peak Tensile Force	Shaft peak tensile strength was tested to failure for each joint using ISO 10555-1, Annex B test methods.	Shaft joint peak tensile force met acceptance criteria.
Hub Peak Tensile Force	Hub-shaft joint peak tensile strength was tested to failure using ISO 10555-1, Annex B test methods	Hub-shaft joint peak tensile force met acceptance criteria.
Coating Integrity – Baseline	Fully assembled devices were inspected under a minimum 2.5x magnification for worst-case coating defects.	Baseline coating integrity characterized with worst-case defect images. Data collected as engineering reference.
Coating Lubricity/Durability	Device coating was evaluated for average frictional force and durability.	Coating lubricity and durability testing met acceptance criteria.
Particulate Testing	Device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model.	Number of particulates generated met acceptance criteria.
Coating Integrity – Simulated Use	Fully assembled devices were pre-conditioned under simulated use conditions in a representative tortuous anatomical model. Coating was inspected under a minimum 2.5x magnification and subsequently tested for average frictional force.	Post-simulated use coating integrity characterized with worst-case defect images.
Kink Resistance	Device was wrapped around a rod of known radius and inspected in-place for any kinks.	Device was resistant to kinking around small radii.
Liquid Leakage	Device was tested for ISO	Liquid leakage met acceptance

Test	Method	Conclusions
	10555-1, Annex C liquid leakage testing.	criteria.
Static/Dynamic Burst	Device was tested under full-length static conditions to burst and at pressures experienced during worst-case dynamic injections.	Static/dynamic burst testing met acceptance criteria.
Torque to Failure	Device was tested for full-length torque strength to determine number of rotations to failure.	Torque to failure testing met acceptance criteria.
Physician Usability Testing	The device was navigated through a tortuous benchtop model to assess compatibility with accessories, device stability, ability to aspirate, ability to inject saline or contrast, and the user's ability to navigate to the M1 and M2 segment of the MCA and retrieve a mechanical thrombectomy device.	All test results met the acceptance criteria.

Performance Testing - Animal

No animal study was performed as there is no change to the indications for use or the fundamental scientific technology for the new devices. Substantial equivalence of the Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter has been established to the predicate device through the results of bench testing.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the new devices. Substantial equivalence of the Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter has been established to the predicate device through the results of bench and design validation testing.